DEC 1 2 2013

K131766
Page 1 of 6

Traditional 510(k) Summary
as required by 21 CFR 807.92(a)

A) Submitted by: APELEM- DMS GROUP
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Contact: Sharyn Orton, Ph.D.
MEDIcept. Inc.
200 Homer Ave.
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B) Date Prepared: October 24. 2013

C) Common Name: System, X-Ray Fluoroscopic, Image-Intensified

Proprietary Name: Platinum dRF Imaging System

Device Regulations and Class: 21 CFR 892.1650. Class II

Product Code: JAA

Classification Panel: Radiology

C) Predicates: K062623 Siemens AXIOM Luminos dRF

D) Device Description:

The Apelem-DMS Platinum dRF Imaging System ("Platinum") is not a stand-alone device. but functions as a platform for FDA cleared or registered components (i.e. generator. panel detector. detector collimator. X-ray tube and software imaging packages), that are installed with a Apelem-DMS manufactured radiological examination table. control panel with system controller software. and electrical panel.

The Platinum dRF remote controlled table is a radiologic table equipped with a flat panel electronic detector. This table is used to perform general digital radiological. fluoroscopy and peripheral angiography. This device allows for treatment on the whole body. using all angles. It allows the user dynamic acquisition for the whole body. to target the zones to analyze. and to be able to track contrast media.

E) Intended Use/Indication for Use: The Platinum dRF Imaging System is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general R/F, diagnostic fluoroscopy, conventional linear tomography, angiography and pediatric examinations.

The Platinum dRF is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image. The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The units may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, digital angiography and digital subtraction angiography (DSA).

The Platinum dRF may be used for outpatient and emergency treatment, as well as for mobile transport (wheelchair and bed) examinations.

The Platinum dRF is not indicated for use in interventional radiology.

F) Comparison to Predicate Device(s):

	Platinum dRF Imaging System	**Siemens AXIOM Luminos dRF K062623**
Product code	JAA	JAA, OWB, OXO
Components		
Flat detector	Trixell Pixium RF 4343 (K080859)	Trixell Pixium RF 4343
Collimator	RALCO R225 ACS (K091517)	Self manufactured
Type	Motorized, remote controlled, with ± 45° manual rotation according to a vertical axis, automatic lighting on, including positioning camera	Motorized up to a maximum of ± 45°, detent at 0°
Field coverage	min 4X4 and max 48X48 at 100 cm source to image distance	min/max not reported
Generator	CMT Indico 100 Series	Self manufactured
Power	50-80 kW	65 kW or 80 kW (optional)
AEC Interface	4 ionization chambers max (solid state ionization 3 fields)	Not available
X-ray tube	Varian 600 kHU tubes RAD92 and G292; 400 kHU tube RAD60	Self manufactured
Use with X-ray ceiling tube	Yes	Yes
X-ray Grid	Smit Rontgen	Self manufactured
Tube motorized rotation	+180°/-180°	+180/-90°

	Platinum dRF Imaging System	Siemens AXIOM Luminos dRF K062623
Oblique projections	45°/-45° motorized adjustment of the height of the rotation axis from 10 to 450 mm above the table (to correct object parallax) The angle is displayed on both the control console and on the table's control panel	40°/-40°: motorized adjustment of the height of the rotation axis from 10 to 300 mm above the table (to correct object parallax) The angle is displayed on both the control console and on the table's control panel
Distance between table-top and detector	6.2 cm	7 cm
Anti-diffusion grid	Oscillating: ratio 10:1, 12:1 / 40l:cm – 60 l:cm / Multifocus 140 cm for exams in the range of 110 to 180 cm : easy ejection from the front of the table	Fixed : ratio 15:1, 80 lignes/cm, f0 = 125 cm, easy ejection from the front of the table
Movement of the AB selector	Max 158 cm (remotely), adjustments by increments up to 6 cm/sec	Max 113 cm (remotely), adjustments by increments up to 7 cm/sec : PERISTEPPING step to step movements of 25 cm each
Compression cone	0-160 N with a compression indication above 3 kg	5-155N
Imaging Software	CMT Thales Duet (K103028)	Flurospot COMPACT digital imaging system
Image resolution	3.4 lp/mm	3.4 lp/mm
Speed	12 f/s (RAD) 18 f/sec for fluoroscopy (large field)	8 f/s (RAD) 15 f/s for fluoroscopy
Dose Reduction	Yes	Yes
DICOM	Yes	Yes
DAP measuring range	0.1 – 99 999 999 µGy.m2	Not available
Pulse frequency	15, 7.5 and 3 pulsed per sec	15, 10, 7.5 and 3 pulsed per sec

	Platinum dRF Imaging System	Siemens AXIOM Luminos dRF K062623
Table specifications		
Table Tilting	-90°/-90° Variable tilting up to 10°/sec Automatic stop in the 0° position is possible / angle indication on the remote control panel as well as the panel on the front of the table.	+90°/-45° or +90°/-90° (optional) Two speeds about 3°/sec and 6°/sec. Time for complete tilt +90° to 0° : 17 sec Automatic stop in the 0° position is possible / angle indication on the remote control panel as well as the panel on the front of the table.
Table top height	50 cm to 130 cm continuously adjustable, about 4 cm/sec 48 cm – 128 cm with the base plate	50 cm to 100 cm continuously adjustable, about 4 cm/sec 48 cm - 98 cm with the base plate not encrusted in the floor
Table top	240 x 85 cm / radio transparent field: 283 x 65 cm / surface inalterable / sliding rail system Equivalent attenuation value : <0.70 mm (+/- 0.1 Al à 100 kV/3.7 mm Al HVL	210 X 80 cm / radio transparent field : 193 x 53.5 cm / surface inalterable / sliding rail system Equivalent attenuation value : 0.65 mm (+/- 0.1 Al à 100 kV/3.7 mm Al HVL
Movement	Laterally; longitudinally 5 way movement: 8 way movement including Z-motion and tilt motion	Laterally; longitudinally 8-way movement
Weight tolerance	265 kg with no restrictions	230 kg
Longitudinal movement of the table top (optional)	150 cm (±75 cm)	160cm (±80 cm)
Transversal movement of the table top	35 cm (±17.5 cm) speed around 6 cm/sec	35 cm (±17.5 cm) speed around 4.5 cm/sec
Patient coverage	201 cm with 2 way 283 cm with 4 way	Not available
Focal distance	110 – 180 cm	115 – 150 cm
Measuring detector/focal point	50 cm	Not available

Substantial Equivalence Discussion

The Platinum dRF Imaging System has a similar intended use, the same technology, and uses identical or the same general components as the predicate device. Components and/or component specifications are nearly identical between the Platinum and predicate device. Compared to the predicate device, the Platinum has larger table specifications, larger rotation ability, and greater movement of the AB selector. These differences are designed to allow for larger, taller patients to be examined and for the examinations themselves to be easier to conduct. This ability has no impact on the imaging functionality of the device, and does not raise new or different issues of safety or effectiveness. All of the features of the Platinum dRF Imaging System are substantially equivalent to the similar features of the predicate device.

Performance

The Platinum is not a stand-alone device, but functions as a platform for FDA cleared or registered components. The Platinum is manufactured with FDA cleared/registered commercially available imaging components. Data as required in the appropriate sections of 21 CFR 1020 have been generated by the appropriate component manufacturer, and included in their manuals. Data generated by Apelem-DMS is limited to that required in CFR 1020.31(e)(1). No additional special imaging performance testing was conducted.

Electrical/EMC testing was successfully conducted per the standards listed below.

Software

The system integration and interconnection software was developed, tested and documented in compliance with FDA Guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff", January 2002.

Conformity to Standards and 21 CFR 1020.30

The Platinum complies with:

- IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-3:2008 Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6 :2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366: 2007 Medical devices -- Application of usability engineering to medical devices
- IEC 60601-2-54:2009 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

- IEC 60601-1-2: 2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- NEMA XR7-1995 (R2000) High Voltage X-ray Cable Assemblies and Receptacles (for the Claymount X-ray Cables)
- NEMA PS 3.1-3.20 (2011) – Digital Imaging and Communications in Medicine (DICOM) Set
- 21 CFR 1020.30, 1020.31 and 1020.32 as applicable

Conclusion

The Apelem-DMS Platinum dRF Imaging System features are substantially equivalent to the similar features of the Siemens AXIOM Luminos predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 12, 2013

Apelem-DMS Group
% Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept, Inc.
200 Homer Avenue
ASHLAND MA 01721

Re: K131766
Trade/Device Name: Platinum dRF Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: October 25, 2013
Received: October 30, 2013

Dear Dr. Orton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131766

Device Name
Platinum dRF Imaging System

Indications for Use *(Describe)*
The Platinum dRF Imaging System is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general R/F, diagnostic fluoroscopy, conventional linear tomography, angiography and pediatric examinations.

The Platinum dRF is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image. The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The units may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, digital angiography and digital subtraction angiography (DSA).

The Platinum dRF may be used for outpatient and emergency treatment, as well as for mobile transport (wheelchair and bed) examinations.

The Platinum dRF is not indicated for use in interventional radiology.

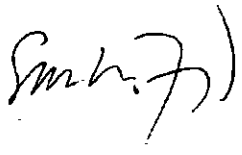
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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